DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

September 3, 2004

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 04-45

Brent Whitesides, President
Whitesides Dairy, Inc.
719 East 700 North
Rupert, Idaho 83350

WARNING LETTER

Dear Mr. Whitesides:

On May 14 and 17, 2004, our investigator inspected your dairy farm located at the 719 East 700 North, Rupert, Idaho. That inspection confirmed that you offered a dairy cow for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You also caused the adulteration of an animal drug because the drug was used in a manner that does not conform to the approved use or the extralabel use regulations at Title 21, Code of Federal Regulations, Part 530 (21 CFR 530, copy enclosed). This caused the animal drug to be unsafe under Section 512(a) of the Act and adulterated within the meaning of Section 501(a)(5) of the Act.

On or about December 13, 2003, you sold a dairy cow identified with back tag number [redacted] and further identified as USDA-FSIS lab report # 435885, for slaughter as human food to [redacted], for slaughter as human food. U.S. Department of Agriculture (USDA) analysis of tissue samples collected from this cow identified the presence of flunixin at 0.408 parts per million (ppm) in the liver. Flunixin is not approved for use in lactating or dry dairy cows (per 21 C.F.R. 522.970, copy enclosed). A food is adulterated under section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of section 512 of the Act, therefore, the presence of flunixin in the edible tissue of this dairy cow caused the food to be adulterated.

Our investigation also found that you hold animals under conditions that are inadequate to prevent animals bearing potentially harmful drug residues from entering the food supply. For example, you lack an adequate system for determining the medication status of animals you offer for slaughter and you lack an adequate system to assure that medicated animals are withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs in edible tissues. Foods from animals held under such conditions are adulterated within the meaning of Section 402(a)(4) of the Act.

Extralabel veterinary use of approved veterinary or human drugs is permitted only if it complies with Sections 512(a)(4) and 512(a)(5) of the Act and 21 C.F.R. Part 530. Our investigation found that your firm used flunixin in an extralabel manner but failed to comply with these requirements. Flunixin was prescribed for extralabel use, and that extralabel use caused an illegal drug residue in a dairy cow sold for slaughter as human food. 21 C.F.R 530.11(c) prohibits any extralabel use that results in a residue which may present a risk to the public health.

Because flunixin was used in an unapproved manner without meeting the requirements for extralabel use set forth in Section 512(a)(4)(A) and 21 C.F.R. Part 530, you rendered the drug unsafe under Section 512 of the Act and adulterated under Section 501(a)(5) of the Act.

It is not necessary for you to have personally shipped an adulterated animal into interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal to be slaughtered for food where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act. Similarly, it is not necessary for you to personally ship an adulterated drug in interstate commerce. The fact that you caused the adulteration of an animal drug that had been shipped in interstate commerce is sufficient to hold you responsible.

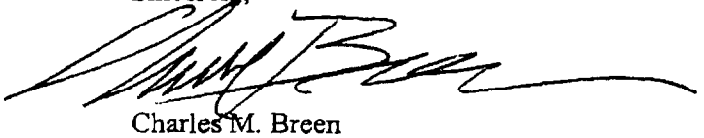
The above is not intended to be an all-inclusive list of violations. As a producer of animals that are offered for use as food, you are responsible for ensuring that your overall operations and the food you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

You should notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Also include copies of any available documentation demonstrating that your corrections have been made.

Please send your written reply to the Food and Drug Administration, Attention: Lisa M. Althar, Compliance Officer, 22201 23rd Drive SE, Bothell, WA 98021-4421. If you have any questions regarding this letter, please contact Ms. Althar at (425) 483-4940.

Sincerely,



Charles M. Breen
District Director